## Somalabs, Inc.

40 Allen Road . South Burlington, Vermont 05403 U.S.A.

Tel: (802) 862-9242

3323

Burlington, Vermont 05406 U.S.A.

Fax: (802) 862-0820

SLFDAN05/04 (S1019EC/HP)

## Notification of a Structure/Function Statement, FFDCA §403(r)(6); 21CFR101.93

To:

Office of Nutritional Products

Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition,

Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740

900 | - 90k

Packer:

SomaLabs, Inc.

40 Allen Road / P.O. Box 4266

SOUTH BURLINGTON, Vermont 05406

Tel: (802) 862-9242 Fax: (802) 862-0820

Text: The gamma-linolenic acid (GLA) present in borage seed oil (Borago officinalis), and the eicosapentaenoic and docosahexaenoic acids (EPA and DHA) present in many marine oils, are respectively members of the omega-6 and omega-3 families of essential fatty acids (EFAs). Because they have already undergone some degree of metabolic transformation in the species from which they are obtained, they are more efficient precursors for eicosanoids (prostaglandins) than are the parent EFAs from these families, linoleic acid (omega-6) and alpha-linolenic acid (omega-3). Eicosanoids are required for the optimal function of many physiological and metabolic systems in the human body. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Name of Dietary Supplement:

Body Shapers™ [enteric-coated softgel capsules].

(Healthy Performance, 207 Pine Creek Road, Wexford, Pennsylvania 15090; private label)

I hereby certify that the information contained in this notification is complete and accurate, and that there is substantiation that the statement is truthful and not misleading.

Date: 20 July, 2005.

Dr. Dennis Jones,

M.A., Ph.D., C.Sci., C.Chem., FRSC(UK), C.Biol., M.I.Biol.

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Signature: